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WASHINGTON, DC 20036				
EXAMINER				
MACFARLANE, STACEY NEE				
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09/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/570,346

Applicant(s)

NAKAGAWARA ET AL.

Examiner

STACEY MACFARLANE

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

1. Claim 2 has been cancelled, claim 3 is amended as requested in the amendment filed on May 12, 2008. Following the amendment, claims 1 and 3-12 are pending in the instant application.

Claims 4-12 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on November 19, 2007.

Claim 3 is under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3. Applicant's arguments filed on May 12, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections

Including New Grounds, Necessitated by Amendment

Claim Objections

4. Claim 3 is objected to because of the following informalities: the term "to form" is repeated one after the other. Furthermore, the wording of the claim is extremely awkward and indecipherable. It currently reads "bringing the cell lysate in contact with a first antibody selected from [two antibodies], to form, to form a first immune complex of

AICD or p53 with the first antibody and to form a second immune complex of the AICD/p53 complex with the first antibody;". The method appears to read upon an immunoprecipitation assay in which either an anti-AICD antibody or an anti-p53 antibody is used to "pull-down" either AICD alone, p53 alone, or a complex of both, and that it is this complex of both proteins is what is called a second complex, and its presence is determined by probing with the antibody that was not used in the first step, which when bound forms a third complex of both antigens and both antibodies.

Clarification is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. As currently amended, Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. As currently amended Claim 3 is indecipherable (see also section 4 above). At the very least Claim 3 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (1) The active steps by which the drug is developed as a drug for the prevention and/or treatment of Alzheimer's disease – if Applicant does not wish the invention to encompass these methods the development of the drug should be limited to the preamble of the claim; (2) the active step by which AICD and p53 are "in the presence

of cisplatin" – it is unclear if this requires co-expression or endogenous expression; (3) the step by which the second and third immune complexes are formed, see also section 4 above.

8. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the claim as previously presented did not specify the presence of cisplatin. It is not clear how this element is related to the requirements of the method.

9. The term "inhibit" of claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for its recitation of a relative term.

Applicant traverses the rejection on the grounds that "inhibit" is reasonable to interpret with its ordinary meaning, which is to repress or restrain a function. This has been considered in full but is not found persuasive for the following reasons.

The term "inhibit" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. Absent such recitation one of ordinary skill in the art would not be reasonably apprised as to the point of reference for inhibition of an interaction between AICD and p53. Therefore, the metes and bounds of the claim are unclear.

10. Likewise, the term "small" in claim 3 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

As currently amended, Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The invention, drawn to a screening method wherein a drug that inhibits the interaction between AICD and p53 is selected for further development of a drug for the prevention/treatment of Alzheimer's, is not supported by either a specific and substantial asserted utility or a well-established utility.

The pending claims have been reviewed in light of the Utility Examination Guidelines 60 FR 36263 (1995) and at 1177 O.G. 146 (1995) and the Revised Utility Guidelines, Vol. 64, Number 244, December 21, 1999.

The Examiner is using the following definitions in evaluating the claims for utility.

"Specific"-A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial"-A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Well-established"-a specific, substantial and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material alone or taken with the knowledge of one skilled in the art.

In Applicant's own words (page 8 of Remarks filed May 12, 2008), as amended the method is directed "to an initial screening process to identify candidate drugs that

have the potential for development for treatment of Alzheimer's disease after further study".

The specification assert the utility of the invention as a method of screening for novel drug/agent based on the premise that the onset mechanism of Alzheimer's disease is different from the amyloid hypothesis (page 2, lines 16-19) and based upon inhibition of an interaction between AICD and p53. The asserted function of the AICD and p53 in Alzheimer's disease is purely hypothetical based upon a putative interaction between the APP intracellular C-terminal domains and p53 (Specification Figure 1). However, with regard to the asserted utilities of the claimed invention, there is no example a real world use for which the method may be used but rather a generic recitation that the method may be practiced for further development or further study of a drug that *may* have the potential for treatment/prevention of Alzheimer's disease. The asserted utility that the invention of the claims can be used as a tool in basic research, such as an initial screening method to identify drugs for further study, does not define a substantial or "real-world" utility. Thus, there is neither a specific utility with respect to a specific drug or class of candidate drugs to be screened, nor is there a substantial "real-world" use defined for the screening method other than an initial process for further development and study.

Therefore, the claimed subject matter is not supported by either a specific or substantial asserted utility because the disclosed utilities are generally applicable to screening methods in general which require further research to identify or reasonably confirm a "real world" context of use. The specification fails to set forth the unique

properties of the claimed invention such that the skilled artisan would recognize a specific real-world utility therefore, and thus, the method of Claim 3 is rejected.

Conclusion

12. No Claim is allowed.

13. This application contains claims drawn to an invention nonelected with traverse in Paper filed on November 19, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Olga N. Chernyshev, Ph.D./
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